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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,115	11/16/2001	James M. Robl	50195/008003	8075

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CLARK & ELBING LLP
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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.	Applicant(s)	
	09/988,115	ROBL ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 10-14, 21, 23-26, 28 and 29, drawn to a transgenic ungulate comprising one or more nucleic acids encoding all or part of an exogenous Ig gene, ungulate somatic cells and methods of producing antibodies, classified in class 800, subclass 14.

II. Claims 6, 7, 15-16 and 18-19, drawn to a transgenic ungulate comprising a mutation that reduces expression of an endogenous antibody and ungulate somatic cells, classified in class 800, subclass 14.

III. Claims 8, 9, 17, 22 and 27 drawn to a transgenic ungulate comprising a mutation that reduces expression of an endogenous antibody and further comprises one or more nucleic acids encoding all of part of an exogenous Ig gene, ungulate somatic cells and methods of producing antibodies, classified in class 800, subclass 14.

IV. Claim 20, drawn to a hybridoma, classified in class 435, subclass 326.

V. Claims 30-38, drawn to a method of producing a transgenic ungulate by transfer of a cell, or its chromatin mass or its nucleus into an oocyte, wherein the cell comprises an mutation in an endogenous antibody heavy chain or light chain nucleic acid, classified in class 800, subclass 24.

VI. Claim 42, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the cell comprise a mutation in an endogenous antibody gene, classified in class 800, subclass 24.

VII. Claim 43, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the

cell comprise a mutation in an endogenous α-1,3-galactosyltransferase gene, classified in class 800, subclass 24.

VIII. Claims 44, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the cell comprise a mutation in an endogenous prion gene, classified in class 800, subclass 24.

IX. Claims 45 and 46, drawn to a method of producing a transgenic ungulate comprising inserting into an oocyte a cell, its chromatin mass or its nucleus, where the cell comprise a mutation in an endogenous J gene or a nucleic acid encoding a J gene, classified in class 800, subclass 24.

X. Claims 47, drawn to ungulate serum comprising human polyclonal immunglobulins, classified in class 424, subclass 130.1.

XI. Claim 48, drawn to ungulate milk comprising human polyclonal immunoglobulins, classified in class 426, subclass 580.

Claims 39-41 link(s) inventions VI-IX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 39-41. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35

U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions I and II are mutually exclusive and independent transgenic ungulates. The transgenic ungulate of Invention I is produced by a materially different and separate protocol than the transgenic ungulate of Invention II, further neither ungulate is needed to implement the other ungulate.

Inventions I and III are mutually exclusive and independent transgenic ungulates. The transgenic ungulate of Invention I is produced by a materially different and separate protocol than the transgenic ungulate of Invention III, further neither ungulate is needed to implement the other ungulate.

Inventions II and III are mutually exclusive and independent transgenic ungulates. The transgenic ungulate of Invention II is produced by a materially different and separate protocol than the transgenic ungulate of Invention III, further either ungulate is needed to implement the other ungulate.

Inventions I-III and IV are distinct because they are of separate uses. The ungulates of invention I-III can be used to produce antibodies or study the role of immunoglobulins in development. The hybridoma of invention IV can be used to produce monoclonal antibodies.

Inventions I-III and V-IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the ungulate can be made by transgenic methods where the gene is injected into a fertilized oocyte.

Inventions I and III, and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the serum of group X can be made by adding human immunoglobulins to ungulate serum.

Inventions I and III, and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the milk of group XI can be made by adding human immunoglobulins to ungulate milk.

Inventions II, and inventions X and XI are mutually exclusive an independent. The transgenic ungulate is not needed to produce either the serum of invention X or the milk of invention XI.

Inventions IV and each of inventions V-XI are mutually exclusive and independent. The hybridoma of invention IV is not required for the implementation of any of the inventions V-XI, and vice versa.

Inventions V-IX are each mutually exclusive and independent inventions. Each of the inventions require materially different protocols as to the donor cell type, whether or not there is a mutated endogenous gene, whether or not there are xenogenous DNA sequences and the particular gene or xenogenous DNA sequences can either encode an antibody, α-1,3-galactosyltransferase, prion or a J chain. These various methods are not required for the implementation of any of the other methods.

Inventions V-IX and inventions X and XI are mutually exclusive an independent. The methods of producing a transgenic ungulate of invention V-IX are not required to produce either the ungulate serum of invention X or ungulate milk of invention XI, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Groups I-XI is not co-extensive with each other, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
March 5, 2004